## REMARKS

***In the Drawings***

In response to the Examiner's objection regarding the subject-matter of claims 38 to 43, Figures 3(a) to (c) and Figures 5(a) to (c) are being amended to identify the flexible member of the mouthpiece with reference signs 57 and 157, respectively. The description at page 17, line 10 and page 23, line 32 is similarly being amended to identify the flexible member of the mouthpiece with reference signs 57 and 157, respectively.

***Double Patenting***

The Examiner has rejected claims 28 and 35 on the ground of non-statutory obviousness-type double patenting based on claim 6 of US-6715485. Applicant traverses this ground for rejection.

Claim 6 is directed to a supply unit for delivering a gas flow separate to an exhalation flow.

The subject-matter of claim 28 is patentably distinct, in requiring cycling of a pressure in the nasal airway of the subject. Claim 6 provides only for the delivery of a gas flow and not cycling of a pressure in the nasal airway.

The subject-matter of claim 35 is patentably distinct, in requiring alternate delivery and withdrawal of a volume of gas through the nasal airway of the subject. Claim 6 provides only for the delivery of a gas flow and not withdrawal of that gas flow.

***Claim Rejections – 35 U.S.C. § 103***

*Claims 1, 3 to 16, 18 to 31, 33, 35 and 36*

The Examiner is alleging that the subject-matter of claims 1, 3 to 16, 18 to 31, 33, 35 and 36 is unpatentable over Djupesland et al (WO-01/97689) in view of Alving et al (US-6019100).

This is not the case. Nevertheless, in the interests of expediency, the independent claims (claims 1, 16, 28, 31, 35 and 36) are being amended further to distinguish over the disclosures of the cited documents.

Each of the independent claims (claims 1, 16, 28, 31, 35 and 36) now requires the supply of ***a metered dose or metered doses of substance*** for delivery to the nasal airway of a subject. Support for this amendment can be found, for example, at page 10, lines 13 and 14 and page 18, lines 13 and 14.

Djupesland et al is directed to a method of and apparatus for collecting airway gases for analysis [see Title and page 1, lines 5 and 6].

In Djupesland et al, the Examiner has identified the embodiments of Figures 5A to 5D. These embodiments provide for the delivery of an exhalation air flow through the nasal airway of a subject, and the Examiner considers the gases contained in the exhalation air flow to be the substance of the claimed invention.

It is acknowledged that the exhalation air flow contains gases, but Djupesland et al makes no disclosure of the supply of metered doses of such gases, in the manner as now required by the claimed invention, and, indeed, is incapable of doing so.

Differently to the claimed invention, Djupesland et al is not concerned with the supply of metered doses of substance to the nasal airway, which typically contains a

medicament, especially systemic or topical pharmaceuticals, or a vaccine in the treatment of a subject.

On the contrary, Djupesland et al is directed to the collection of airway gases and is incapable of supplying metered doses of substance to the nasal airway. The Examiner has identified the collection reservoir (330) of Djupesland et al as the substance supply unit of the claimed invention, but the collection reservoir (330) is nothing more than a conduit through which the exhaled air flow is directed to the nasal airway and is incapable of supplying metered doses of substance.

As regards Alving et al, which is directed to a ventilator device, it is submitted that the skilled person would have had no conceivable motivation to contemplate the application of the teaching of Alving et al to Djupesland et al.

As discussed above, Djupesland et al is directed to a method of and apparatus for collecting airway gases for analysis [see Title and page 1, lines 5 and 6], and essentially requires closure of the oropharyngeal velum, whereas, contrarily, Alving et al is directed to the ventilation of the nasal airway using a ventilator [see column 4, lines 43 to 46] for the purpose of delivering endogenous, biologically-active agents, such as NO, to the lower airways, which necessarily requires the oropharyngeal velum to be open.

The teachings of Djupesland et al and Alving et al are entirely incompatible, and this would have been clearly understood by the skilled person.

This should be particularly clear from a consideration of the embodiments of Figures 5A to 5D of Djupesland et al, to which the Examiner has referred, which require that an oral exhalation airflow is developed through a mouthpiece (310) to close the oropharyngeal velum, and this exhalation airflow is delivered into one nostril via a first, inlet nosepiece (311), through the nasal airway and out of the other nostril via a second, outlet nosepiece (312). With this requirement for closure of the oropharyngeal velum, to

allow for collection of the airway gases, the apparatus of Djupesland et al would not allow for aspiration of the nasal airway, to achieve delivery to the lower airways, in the manner as required by Alving et al.

In summary, it is submitted that the subject-matter of the independent claims (claims 1, 16, 28, 31, 35 and 36) is patentably distinguished over the disclosures of Djupesland et al and Alving et al.

As regards the dependent claims, it is submitted that these claims are allowable, in being dependent upon allowable independent claims.

*Claims 38 to 43*

The Examiner is alleging that the subject-matter of claims 38 to 43 is unpatentable over Djupesland '672 (WO-00/51672).

This is not the case. Nevertheless, in the interests of expediency, claim 38 is being amended so as to distinguish further over the disclosure of Djupesland '672.

Claim 38 now expressly requires that the flexible member, which is deflectable on exhalation into the mouthpiece, be a ***closed*** flexible member.

Support for this amendment can be found at page 17, lines 10 to 16 and page 23, line 32 to page 24, line 5. These passages disclose that the flexible member (a diaphragm) (57, 157) be such that no part of the delivery device (11, 111), other than the mouthpiece (31, 131), be exposed to the exhalation breath of the subject. This can only be achieved if the diaphragm (57, 157) closes the flow path from the mouthpiece (31, 131).

In Djupesland '672, the Examiner has identified the embodiment of Figure 9, and the element (116) as the flexible member of claim 38.

Firstly, Djupesland '672 makes no disclosure or suggestion of the element (116) being flexible. Indeed, it is submitted that the element (116) cannot be flexible, at least insofar as it is required to be deflected by an exhalation airflow, as the element (116) is required to rotate on a threaded shaft [see page 29, lines 2 to 4], and flexing would prevent such rotation.

This notwithstanding, the element (116) of Djupesland '672 is not a closed member, as now required by claim 38. Djupesland '672 requires essentially that a flow [see page 29, lines 6 to 12 and Figure 9 (arrow)] is delivered thereover and from the nosepiece (132). Such a flow could not be achieved if the element (116) were to be a closed member, in the manner as now required by claim 38, and the skilled person would thus not conceivably have contemplated modification of the device of Djupesland '672 to utilize a closed flexible member in place of the rotatable element (116).

In summary, it is submitted that the subject-matter of claim 38 is patentably distinguished over the disclosure of Djupesland '672.

As regards the dependent claims, it is submitted that these claims are allowable, in being dependent upon allowable claim 38.

## CONCLUSION

Applicant respectfully submits that all pending claims are in condition for allowance and requests early favorable action. If the Examiner believes a telephonic interview would expedite prosecution, the Examiner is welcome to contact Applicant's Agent at the number below.

Respectfully submitted,

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